

REMARKSStatus of the Application and Claims

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 1-12 and 14 in condition for allowance.

Applicants submit that the proposed amendments of claims 1-12 and 14 does not raise new issues, introduce new matter or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

OBJECTIONS

The Office objected to the specification because a statement of the status of priority applications was not present. Applicants have amended the specification to add a statement of priority, including the status of the parent application. This amendment does not add new matter. Applicants respectfully request that the objection be withdrawn.

35 U.S.C. § 112, SECOND PARAGRAPH

The Office maintained rejections of the claims as being indefinite and failing to particularly point out and distinctly claim the subject of the invention, which had been made in the previous Office Action. The Office also asserted that any new rejections were the result of amendments made to the claims.

Specifically, on page 3, the Office rejected claims 9, 10, 11, 12, 13, and 15 because it asserted that the word "gene" is unclear. Applicants have amended these to recite "DNA of interest" instead of "gene", as the Office suggested.

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On page 3, the Office put forth several rejections of claim 1. First, the term "embryo derived cells" was rejected as being unclear because it was asserted that this term encompasses all cells of the plant. Applicants have deleted the term "embryo derived cells", thus obviating the grounds for this rejection. Applicants respectfully request that the rejection be withdrawn.

Second, the Office rejected claim 1 because it asserted that the term "a vector or direct DNA transfer" is unclear. The Office was unclear about the difference between transforming a cell with a vector or by direct DNA transfer, but Applicants respectfully note that these are terms of art easily understood by one of skill in the art. The term "vector" implies that other DNA sequences, in addition to the DNA of interest, guide the transformation, while the term "direct DNA transfer" implies that the DNA of interest is transformed directly, without the use of other DNA sequences.

Third, the Office rejected claim 1 because it asserted that a transforming step is missing. Applicants have amended claim 1 to replace the term "delivering" with the term "transforming" and respectfully request that the rejection be withdrawn.

Fourth, the Office asserted that the term "transformation" lacks antecedent basis. Applicants have deleted this term and replaced it with the term "method of transforming," which has antecedent basis in the preamble of the claim.

Finally, the Office asserted that the claim is incomplete because the final step of the method does not produce the recited final product. Applicants have added a step to the claimed method, which recites "(d) obtaining a transformed *Allium* genus plant;" This step provides that the final product is produced. Therefore, Applicants respectfully request that the rejection be withdrawn.

The Office also rejected claims 4 and 5 under 35 U.S.C. § 112, second paragraph, because the term "the embryos" was found to lack antecedent basis. See Office Action at page 4. Applicants have amended claims 4 and 5 to recite "the embryo cells", which has antecedent basis in claims 1 and 2, from which these claims depend.

The Office also rejected claim 5 because it found that the term "active T-DNA" is unclear. See Office Action at page 4. Applicants have amended this term to recite "T-DNA active for transformation," and respectfully request that the rejection be withdrawn. Furthermore, the Office rejected claim 5 because it found the term "immediate" to be unclear. Applicants have deleted the term "immediate" and respectfully request that this rejection be withdrawn.

The Office rejected claim 7 for several reasons. See Office Action at page 4. First, it found the element of a transformation step to be missing. Applicants have amended claim 7 to add "transforming the immature embryos" to step (b). The Office also rejected claim 7 because it asserted that the claim is incomplete in not reciting a final step that produces the final product. Applicants have further amended claim 7 to add a step "(g) producing a transformed Allium genus plant." Furthermore, the Office asserted that the term "cultures" in step (b) lacks antecedent basis. Applicants respectfully note that the term "cultures" was previously deleted from step (b) of claim 7, thus obviating a response at this time. Finally, the Office asserted that the term "embryos," in claim 7 steps (c) and (d), lacks antecedent basis. Applicants have amended this term to "immature embryos." For these reasons, Applicants respectfully assert that the terms of claim 7 are definite and request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

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On pages 4-5, the Office maintained the rejection of claims 13 and 15 because it found Applicants argument that the term "modified alliinase gene" means an alliinase gene that is over-expressed, temporarily or spatially expressed, or has suppressed expression of its gene product. Instead, the Office offered an entry in the Webster's Dictionary defining "modify" as "change in form or function." Applicants traverse this rejection because "the ordinary meaning must be determined from the standpoint of a person of ordinary skill in the relevant art." *Teleflex, Inc. v. Ficosa North Am. Corp.*, 63 U.S.P.Q.2d 1374, 1380 (Fed. Cir. 2002). Therefore, the ordinary meaning of the term "modified" is the meaning ascribed to it by Applicants, which is the meaning used by those in the field of molecular biology and related fields, and not the meaning provided in a dictionary of general usage. Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 112, FIRST PARAGRAPH

The Office rejected claims 1-15 because it asserted that they were not enabled and contain subject matter not described in the specification. Applicants traverse this rejection. Applicants note that the Office's characterization of the invention is not correct. On page 6, lines 8-9, the Office describes the invention as a method of transforming an Allium genus plant comprising steps (a), (b), and (c), "wherein the transformation is carried out *with* passage through the callus phase, . . ." In fact, the claimed invention is performed *without* passage through the callus phase. Independent claim 1 recites "wherein the method of transforming is carried out *without* passage through a callus phase" (emphasis added), and independent claim 7 recites "transforming the *immature* embryos by inoculating the immature embryos with an

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Agrobacterium strain . . . ,” indicating that the embryos have not passed through the callus phase.

Furthermore, Applicants note that the Office admits that the claimed invention is enabled. On page 7, the Office indicates: “Even if Applicant were enabled, this [sic] would be enabled only to the extent of claims limited to a method of transforming an Allium genus plant, as described in the specification (page 5, line 11 through page 6, line 14).” Applicants assert that they are claiming methods provided in the specification. Specifically, Applicants are claiming transformation of an Allium genus plant wherein the transformation is carried out in immature embryos. This is the method described in the specification. By the Office’s admission, therefore, the claimed methods are enabled and Applicants request the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

The Office also argued that the terms “a modified alliinase” and “a modified gene” lack guidance in the specification. See Office Action at 9-10. Although the Office did not indicate to which claims this argument relates, presumably it relates to claims 13 and 15, which recited these terms. Applicants have canceled these claims, and request that any rejection in light of these terms be withdrawn.

Applicants note that the argument recited by the Office in the context of this 35 U.S.C. § 112, first paragraph, rejection (“Applicant has carried out sufficient research to demonstrate that this (microparticle) method of wounding plants [sic] cells will not deliver the vector or DNA . . . into a complete fertile plant.”) has been mischaracterized. Applicants did not make this assertion in response to a rejection under § 112, but instead to distinguish the claimed invention from that disclosed in Bidney, in response to rejections under 35 U.S.C. § 102 and 103. See Amendment of May 16, 2003, at page

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11. Applicants went on to state that this research showed that this method, which was disclosed in Bidney and is distinct from the claimed method, never achieved successful transformation. It appears, though, that the Office is using this statement to support its assertion that the claimed method is not enabled. Applicants traverse any rejection the Office may be making in regard to Applicants' statement and request that the rejections under 35 U.S.C. § 112, first paragraph be withdrawn.

35 U.S.C. § 103

The Office maintained the rejection of claims 1-6 and 8-12 as being obvious in light of Bidney (EP 0 486 234 A2). Although this rejection is similar to the one made in the previous Office Action of December 17, 2002, Paper No. 6, the Office has not indicated that it considered Applicants arguments, and whether those arguments were found persuasive. If they were found not to be persuasive, it is not clear to Applicants, without remarks from the Office, as to why. In the absence of any stated reason that Applicants' earlier arguments were deemed unpersuasive, Applicants will expand upon those arguments here. Moreover, Applicants also wish to thank the Examiner for the opportunity to discuss these concerns in a telephone conference on January 5, 2004.

Although Bidney proposes that the disclosed method "can be employed with any desired agronomic or horticultural species, . . ." and continues by listing 75 different plant species, including onion, see Bidney at 3, line 55, et seq., there is no evidence in Bidney that the disclosed method successfully transforms each of these species. In fact, the only species that Bidney demonstrates can successfully be transformed with the disclosed method is sunflower, a dicot species. See Bidney, Example IV, at 6, lines 26-50.

In contrast, the claimed method is a method for transforming the monocot species, *Allium*. Applicants noted in the specification that there was a need in the art for a method of transforming *Allium*, even after other methods were known, because these methods, like that disclosed by Bidney, were useful only for the successful transformation of other species. Specifically, Applicants stated: "There are no published protocols for the transformation and regeneration of Allium species." Specification at 1, lines 11-12. Applicants further explained that there were incompatibilities between methods of transforming different species and therefore there was a need for a method that was successful with *Allium* species, as follows:

Recently, *Agrobacterium*-mediated transformation of monocotyledons has gained favour and many monocotyledonous species (including rice, wheat, barley, maize and sugarcane) have now been transformed using this method. A key component in the success of these systems has been the transfer of DNA to callus cell types (usually derived from the pre culture of embryo tissue) followed by regeneration from these callus cells using precise post transformation selection protocols.

Transformation of *Allium* callus is not useful as regeneration from callus is extremely difficult.

Specification at 1, lines 21-28. Accordingly, Bidney does not disclose a method that is enabled for transforming monocotyledonous *Allium*, but only a method that successfully transforms dicotyledonous sunflower plants.

The specific method taught by Bidney is also lacking all of the elements of the claimed invention, specifically the transformation of embryo cells. Bidney provides a method for "culturing tissues of the species and genotype to be transformed" and bombarding the cultured tissues with *Agrobacterium* microparticles to regenerate the transformed cells. See Bidney at 3, lines 14-21. Bidney also discloses that the "[t]issues can come from any desired plant part" Bidney at 4, line 10 (emphasis added),

and that preferred tissues from which the transformation host is *derived* includes "immature embryos", *id.* at line 12 (emphasis added). This disclosure does not specify that embryo tissue is transformed. In fact, when read in its entirety, Bidney teaches or suggests that embryo cells are not transformed directly. In Example IV, the only example to demonstrate transformation, sunflower seeds were allowed to germinate and then were cultured for more than one day to derive apical meristem tissue, before transformation. See Bidney at 6, lines 28-35. This germinated and cultured tissue has progressed beyond the embryo stage, indicating that embryos are not used in the method disclosed by Bidney. Embryos are required, though, in the claimed invention.

Indeed, the Office has admitted that "Bidney does not teach a method where embryos are inoculated immediately following their isolation." Office Action at page 11, lines 6-7. Without the element of transformation of embryo cells, Bidney cannot render the claimed invention obvious. See *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art.")

Furthermore, the method disclosed by Bidney differs from Applicants' claimed method because it relies on particle bombardment. As discussed in Applicants' May 16, 2003 Amendment at p. 11-12, Applicants' own experiments using microparticles and wounding of plant cells show that this method does not deliver a vector or DNA to cells that are both competent to receive and integrate foreign DNA and are capable of subsequently regenerating into complete fertile plants. See *Plant Cell Rpts.*, 15(12):958-962. The Applicants enclose herewith a declaration discussing the findings of those experiments. See Colin Eady Rule 1.132 declaration. Therefore, the method disclosed in Bidney is not successful with Allium species, as is the claimed method.

Finally, the Office asserted that "Bidney does not teach regeneration of embryonic cultures with a callus phase." Office Action at 11, lines 2-3. From the Office's assertions, Bidney does not teach or suggest a method of transforming, wherein the "transforming is carried out without passage through a callus phase." This element, of course, is a necessary element of the claimed invention. Because methods of transformation differ between different species, and Bidney provides no direction or expectation of success in transforming onions or Allium, but only for sunflower, Bidney provides no motivation to one of skill in the art to practice the claimed invention. Without disclosure of each and every element of the claimed invention, or motivation to practice each and every element, M.P.E.P. § 2141, Bidney does not render the claimed invention obvious, and Applicants respectfully request that the rejection be withdrawn.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

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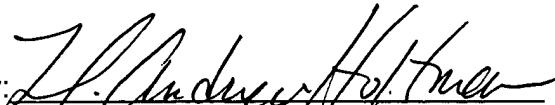
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Respectfully submitted,

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